K130297
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PALODEX GROUP

MAY 29 2013

510(k) Summary

Date: February 4th, 2013

PaloDEx Group Oy

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Manufacturer:

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Tel: +358 10 270 2000
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Contact person: Mr. Matti Tulikoura, Tel +358 400 609 507

Trade Name:
SCANORA 3Dx

Common Name:
Cone beam 3D X-ray system

Classification Name:
Computed tomography x-ray system (21 CFR § 892.1750, product code OAS)

Description:
Scanora 3Dx is a Cone Beam Computerized Tomography x-ray system for Dentomaxillofacial and Head & Neck (ENT) imaging. Dedicated panoramic imaging is an option. In CT mode it generates a conical x-ray beam during rotation around a patient's head and produces two dimensional projection images on a flat panel detector. Three dimensional images are then reconstructed and viewed with 3rd party software. In panoramic mode panoramic and TMJ images can be taken in the classical way on a separate CCD detector.

Intended Use:
The unit must only be used to take 3D and (optional) panoramic images of the dento-maxillo-facial complex and the head and neck areas, including the ear, nose and throat (ENT) areas of the human skull. The unit must not be used to take images of any other part of the human body.

Note that panoramic and 3D exposures should not be used if conventional intraoral radiographic images (bitewing exposures) would suffice.
Note that cone beam computerized tomography images are not adequate for the analysis of soft tissue.
Always use the lowest possible exposure values that will allow you to take an image of sufficient quality for you to perform the required diagnostic examination.

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Indication For Use

SCANORA 3Dx is a Cone Beam 3D x-ray system for imaging the head and neck areas, including the ENT and dentomaxillofacial areas, for use in diagnostic support. Dedicated panoramic imaging is an option. A flat panel detector is used to acquire 3D images and an optional CCD sensor to acquire panoramic images. The device is operated and used by qualified healthcare professionals.

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Summary of Technological Characteristics:
SCANORA 3Dx is substantially equivalent in design, composition and function to the current SCANORA 3D unit [K110839].

Concept		SCANORA 3Dx	SCANORA 3D [K110839]
1.	X-ray source	3D mode: 90 kV, 4-10 mA, pulsed. Pan mode: 60-81 kV, 4-8 mA continuous. kV accuracy +/5kV. Same x-ray source for 3D and Pan modes.	3D mode: 90 kV, 4-12.5 mA, pulsed. Pan mode: 60-81 kV, 4-8 mA continuous. kV accuracy +/5kV. Same x-ray source for 3D and Pan modes.
2.	Focal spot	0.5 mm	0.5 mm
3.	Image detector(s)	Amorphous Silicon Flat Panel + CCD for panoramic imaging	CMOS Flat Panel + CCD for panoramic imaging
4.	3D imaging technique	Reconstruction from 2D images	Reconstruction from 2D images
5.	3D's Field Of View	H50 x Ø50 mm H50 x Ø100 mm H80 x Ø100 mm H140 x Ø100 mm H80 x Ø165 mm H140 x Ø165 mm H180x Ø165 mm - Stitched H240x Ø165 mm - Stitched	H60 x Ø60 mm H75 x Ø100 mm H75 x Ø145 mm H130xØ145 mm - stitched
6.	3D's total viewing angle	360 degrees	360 degrees
7.	Pixel size	Amorphous Silicon flat panel: 120 / 240 µm CCD for panoramic imaging: 48 µm	CMOS flat panel: 200 µm CCD for panoramic imaging: 48 µm
8.	Voxel size	100/150/200/250/300/350/400/500 µm	133/200/250/300/350 µm
9.	3D scan time	18 - 34 sec	10 - 26 sec
10.	3D's effective exposure time	2.4 - 6 sec	2.25 - 6 sec
11.	Indications for use	Scanora 3D is a Cone Beam 3D x-ray system for imaging the head and neck areas, including the ENT and dentomaxillofacial areas, for use in diagnostic support. Dedicated panoramic imaging is an option. A flat panel detector is used to acquire 3D images and an optional CCD sensor to acquire panoramic images. The device is operated and used by qualified healthcare professionals.	Scanora 3D is a Cone Beam 3D x-ray system for imaging the head and neck areas, including the ENT and dentomaxillofacial areas, for use in diagnostic support. Dedicated panoramic imaging is an option. A flat panel detector is used to acquire 3D images and an optional CCD sensor to acquire panoramic images. The device is operated and used by qualified healthcare professionals.
12.	System footprint	H197cm x D140cm x W160cm	H197cm x D140cm x W160cm
13.	Weight	310 kg	310 kg

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Non-clinical Test Data:
Preference study as an image quality comparison between Scanora 3Dx and the predicate device was performed. Same phantom was imaged with Scanora 3Dx and the predicate Scanora 3D. The results were evaluated by internal reviewers. Validations have been performed successfully to ensure the safety and effectiveness of the Scanora 3Dx system.

Clinical Test Data:
Clinical testing has not been conducted on Scanora 3Dx device because CBCT imaging technique and FBP algorithm are widely used. Only a preference study was conducted.

Conclusion:
Based upon the similar technological/performance characteristics to the predicate device and the successful validation of the SCANORA 3D software, the clinical performance of the SCANORA 3Dx is deemed to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2013

PaloDEx Group Oy
% Mr. Matti Tulikoura
Regulatory Manager
Nahkelantie 160
Tuusula 04300
FINLAND

Re: 510(k) Number: K130297
Trade/Device Name: SCANORA 3Dx
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: April 21, 2013
Received: April 29, 2013

Dear Mr. Tulikoura

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

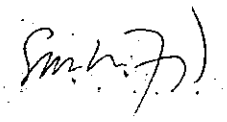
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130297

Device Name: SCANORA 3Dx

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K130297